THE USE OF A POROUS ALUMINA CERAMIC WEDGE IN TIBIAL VALGISATION OSTEOTOMY BY INTERNAL OPENING

50 cases with a mean follow-up of 16 months

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RESUME

The purpose of this work is to study the behaviour of a porous alumina ceramic wedge used as a spacer during the process of bone consolidation in the context of the valgus tibial osteotomy by internal opening fixed with a screw plate.

From October 1994 to December 2000, 50 cages were used. The series had a classic female predominance (31 women for 19 men, mean age 55 at the date of surgery, 26 right knees and 24 left). The mean follow-up is 16 months, 26 cases with more than two years of development, 37 more than 6 months. Two patients were lost to the study at 5 and 6 months after consolidation.

The results of the tibial osteotomy were consistently good. A single correction loss with screw failure in an obese patient was observed. Bone consolidation was obtained in all cases and no complication specific to the wedge was demonstrated. Bone integration was radiologically satisfactory. Nine rims around the wedge, out of 37 cases (24%), were detectable at 6 months of minimal recoil without affecting the result.

The inert ceramic wedge thus appears to represent, in the context of the tibial valgus osteotomy, an attractive alternative to the use of resorbable bone substitutes.

Key words: knee osteoarthritis, tibial valgisation osteotomy, osseous substitutes, knee.

INTRODUCTION

The purpose of this work is to study the behaviour of inert porous alumina ceramic wedges in tibial valgisation osteotomy by internal opening.

This study was not initiated to assess the results of the osteotomy of addition, which has already been concluded [Hernigou (1), and Debeyre Artigou (2), Goutallier et al. (3)] but to appreciate the evolution of the ceramic wedge during the bone consolidation phase.

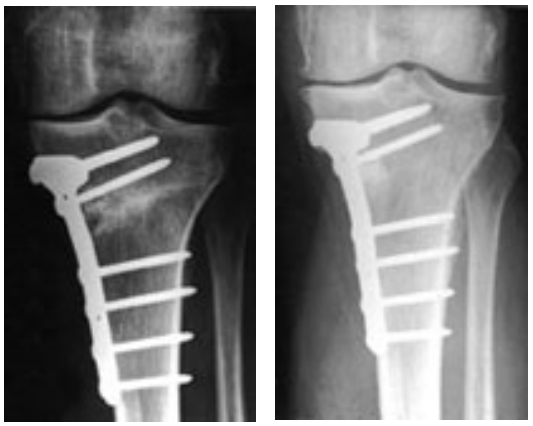

Fig. 1 – Tibial osteotomy by medial insertion
a) Radiographic aspect at 1 year
b) At 2 years

The function of the wedge was to maintain the opening during the period of bone reconstruction *(Fig. 1),* in the manner of the acrylic cement spacer used by Goutallier et al. (4). It did not have the role of filling which can be assigned to a bioactive and / or resorbable bone substitute.

Moreover, alumina is a bio-inert material and does not constitute "stricto sense" a bone substitute [Hadamouche and Sedel (5)]. The porous nature of the ceramic used was considered a potential advantage; In fact, the osseous colonization of its open porosity *(fig.2)* was able to avoid an interposition at the bone-material interface, possible site tissue reactions; On the other hand, it could contribute to the stabilization of the hold and therefore of the osteotomy.

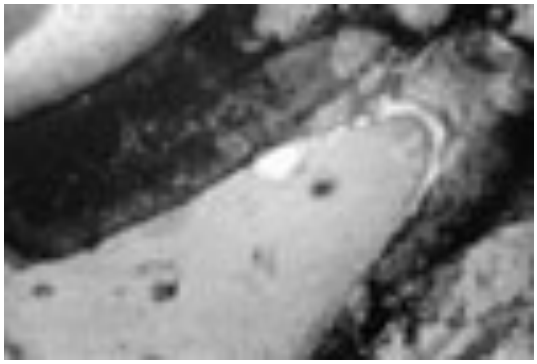

Fig. 2 – Histologic section visualising the bone regrowth after 7 months of implantation in a Beagle dog (in clear the neo-formed bone spans with the implant making up the darkened area: magnification x 100

The stability of the assembly has always been protected by a standard internal osteosynthesis plate [Hernigou (6)], and then later by a plate similar but slightly modified, in particular by pre-shaping, allowing an immediate adaptation to the morphology of the proximal tibial metaphysis of the man and the woman and by increasing the number of screws (6 in women and 7 in men), in order to increase the mechanical properties *(fig.1).*

MATERIAL AND METHOD

From October 1994 to December 2000, 50 porous alumina ceramic wedges have been used during a tibial valgus osteotomy performed by medial approach in the context of the medial tibial femoral osteoarthritis of varus knee.

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The bioceramic wedge

The implant utilized was a porous alumina ceramic wedge in the form of a parallelepiped rectangle, one of the sides of which allowed to maintain a tibial opening increasing from 5 to 17 mm [Hernigou et al. (7)], these extreme openings appearing to be at the reasonable limit of the indication [Vielpeau (8)].

The technology utilized has made it possible to obtain a ceramic with high mechanical resistance (the wedges can be stressed by compression up to a value of 60 MPa (i.e. 600 kg / cm 2), these wedges are also non-absorbable and bio-inert. Due to these qualities it is considered as a reliable mechanical support capable of preventing any loss of correction when pressure is exerted onto the operated limb.

Moreover, thanks to a controlled porosity (open porosity of 200 to 600 microns in size and a relative porosity of 60%), bone penetration into the wedge will occur. The repairing bone tissue has no resorption work as is the case with the use of a bone substitute [Gouin et al. (9), Daculsi et al. (10)], the wedge ultimately becomes an integral part of the bone, with durable osteo-integration.

The 13 manufactured wedges were sterilized with 25 Kgy gamma rays and then packaged in a rigid double pack and a peelable vacuum bag. The alumina used was in accordance with standard NF S 90-804 requirements. The porosity provided for a mechanical resistance by compression adapted to the predictable stresses that can possibly be exerted on the wedge. This material received the CE 0318 certification in March 1998. In the absence of any innovation concerning the surgical technique (tibial valgisation by internal addition) or the implanted material (alumina ceramic), both of which have been in use for decades, the surgical procedure has not been submitted to the CCPPRB (Committee to protect individuals in biomedical research).

The series

Fifty cases were collected (31 women, 19 men, mean age 55 years, 35-69 years, 26 right knees, 24 left). The etiology has always been medial femoral-tibial unicompartmental osteoarthritis on genu varum. These were knees unscored from any intervention except in one case (preliminary meniscectomy).

All patients underwent pre- and post-operative radiographic assessment including the last follow-up, including bilateral face-to-face support, bilateral pediatric profile, femoral-patellar incidence at 30° flexion and a pangonogram in immediate preoperative, at D + 8 and at one year. The mean pre-operative angular deviation was 4° of varus (extremes of 1° valgus to 15° varus, 21 varus deviations greater than or equal to 5°). The average thickness of the wedge was 10 mm (extremes of 5 to 17 mm).

All patients were reviewed again at D + 21, D + 45, at 3 months, at 6 months, at one year and then every 2 years and examined by the surgeon. The clinical and radiological records of all patients were considered to be exploitable. Bone consolidation was assessed by the usual gradual disappearance from outside of the tibial osteotomy line and the appearance of bone spans bridging the inter-fragmentary space with particular attention being paid to the presence of bone condensation of the fractured margins, which may lead to a delay in consolidation. Similarly, bone regrowth was studied in the direct vicinity of the wedge and in particular the occurrence of edges around the periphery of the implant. The mean follow-up was 16 months (range 1 to 66 months), 26 cases were more than 2 years old, 37 were more than 6 months old. Two patients were lost to follow-up at 5 and 6 months of intervention, with bone consolidation acquired during the last control.

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RESULTS

Complications

No thromboembolic or septic complications were observed. Three lines of splitting of the external tibial plateau or of the mass of the spines did not modify either the final result or the correction. The ablation of the plaque was necessary in a patient because of pain and made it possible to note the perfect macroscopic osteo-integration of the wedge *(figure 3).*

A fracture of the distal screws in an obese patient (122 kg for 1.74 m) with loss of the correction (4 ° of valgus to 2 ° of varus) was observed *(Figure 4).*

No complications specific to the wedge were noted and removal was never considered as necessary.

Fig. 3- Radiographic aspect of the osteo-integration of the wedge at 5 years, after ablation of the plate.

Functional results

Functional results (pain, maximum walking perimeter, painless walking perimeter, use of walking sticks, stair climbing, mobility) were good and especially the recovery of joint mobility: the mean postoperative flexion was 125 ° (from 90 to 140 °) and the mean extension of 0.1 ° (-5 to + 5 °).

Radiographic results

Bone consolidation

Bone consolidation was obtained at 3 months on average in all but two cases where it was only obtained at 8 and 13 months, without any consequence on the final result.

The angular correction

The mechanical axis of the lower limb was postoperatively at 4.3° of valgus on average (1° varus at 10° valgus), 88% or 31 patients out of 35 interpretable immediate postoperative pangonograms in the ideal range of 3° to 7° valgus [Hernigou (11)].

The mechanical axis at one year of follow-up was on average 4.0° valgus (2° varus at 10° valgus, 21 patients out of 31 pangonogammes at one year - 68% - being within the ideal range).

Seven patients (23%) suffered a loss of correction, the loss being 3° maximum in 5 of the 7 cases. One of the two remaining cases was that of the obese patient with fracture of the osteosynthesis material (*Figure 4)*, the second one of a 42-year-old woman at the time of the operation, with a loss of 4° (5° valgus to 1° valgus), without breakage of the material.

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Presence of edging or lines

At 6 months of minimal follow-up (37 of the 50 cases of the series), there were only 9 fine (24%), non-evolving, thin lines less than 1 mm thick. Their presence did not affect the final result, these small edges were moreover often only visible on frontal incidences. Their tendency to spontaneously and progressively disappear was confirmed as the series follow-up increased *(Figure 5).*

Fig. 4 – Fracture of the osteosynthesis material with progressive loss to angular correction.
a) Radiographic aspect at D + 21
b) Radiographic aspect at 6 months

DISCUSSION

Opening wedge tibial osteotomy by medial approach is advocated by many authors [Goutallier et al. (3), Neyret and Dejour (12)]. The main advantages of such an osteotomy result paradoxically from the rise of total knee arthroplasty (Absence of major metaphyseal vicious callus if one knows to remain within the reasonable limits of the angular correction, namely a wedge less than 20 mm thick, medially scar easily reusable in case of subsequent arthroplasty, modular patellar lowering) [Moulin-Traffort *et al.* (13), Katz *et al.* (14). Windsor *et al. (15)].*

Debeyre and Artigou (2) insisted on the need to obtain a stable mounting of the osteotomy and in particular to associate a filling corner with an internal plate, the mechanical strength of which contributes to the strength of the assembly.

In addition to the disadvantages of the iliac graft (postoperative morbidity of the sampling site, the difficulty of its shaping affecting the accuracy of the angular correction), [Laurie et al. (16), Summers and Eisenstein (17), Cockin (18)], its mechanical strength is particularly poor due to the remodelling phase throughout the duration of the osteotomy consolidation. Other filling materials and bone substitutes proper that are resorbable or inert material such as cement wedge [Goutallier et al. (4)] and the inert alumina ceramic wedge have been developed to overcome these disadvantages.

It is difficult to establish a significant comparison of the behaviour of the inert alumina ceramic wedge with those of resorbable bone substitute and in particular mechanically due to the diversity of such substitutes and their variable mechanical resistance from one product to another and especially in time, after implantation, as evidenced by several studies [Gouin et al. (9), Daculsi et al. (19), Flatey et al. (20), Trécant et al. (21)].

The alumina ceramic wedge exhibited the expected long-term mechanical strength throughout the consolidation period. The operative angular correction showed only two significant losses, one of which was attributable to obesity in the patient concerned.

The long-standing use of alumina ceramic in total hip arthroplasty with extensive bone contact has demonstrated the bio-inert nature of the material which appears to lack cytotoxicity [Hamadouche et al. (22)]. In our series, the total absence of signs of intolerance (infection, inflammation, rejection) as observed with certain filling materials can be attributed to this same bio-inertia.

As far as re-habitation is assumed to correspond to the absence of edging or lines, the interest of the porosity in the role attributed to the alumina is confirmed by the low rate of edges or lines and their tendency to progressively disappear.

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The reduced volume of the wedges, which is a favourable result of their mechanical strength, and the absence of any sign of intolerance makes it possible to predict their retention in place during total arthroplasty. The use of resorbable filling is therefore not necessary. Finally, the time of perioperative preparation of an acrylic cement wedge is avoided, avoiding to prolong a thrombogenic intervention under tourniquet.

Overall, the functional results in our series, with regards the tibial osteotomy proper, do not differ from those found in the literature and in particular the analgesic effect, articular mobility, autonomy, angular correction and maintenance both clinically and radio-graphically.

Fig. 5– Habitual evolution of edging / line around the wedge.

a) Radiographic aspect at D + 45

b) Radiographic aspect at 1 year

CONCLUSION

The use of the porous alumina ceramic wedges in tibial valgisation osteotomy has given us complete satisfaction. The review of the first 50 implantations shows that the results of the intervention are perfectly in line with the data of the literature, without any specific complication due to the wedge. Its ease of use, its safety, its satisfactory mechanical strength and invariable in time allowing complete consolidation of bone, its radiological osteo-integration allowed us to consider it as a reliable alternative to the use of any other material, whether absorbable or not, in this type of intervention.

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